In the New York State Courts

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Eastern District of New York Dismisses Constitutional and Title VII Challenge to the New York State COVID-19 Vaccine Mandate for Health Care Workers

Does 1-2 v. Hochul, No. 21 Civ. 5067, 2022 WL 4637843 (E.D.N.Y. 2022). On Aug. 26, 2021, the New York State Department of Health adopted an emergency regulation, codified at 10 N.Y.C.R.R. § 2.61 ("§ 2.61" or the "Mandate"), which requires hospitals, nursing homes, and other covered entities to ensure that their patient- and staff-facing workers are "fully vaccinated" against COVID-19. The state's Public Health and Health Planning Council (PHHPC), which issued the rule, released a Regulatory Impact Statement stating that the Mandate was driven by a 10-fold increase in cases of COVID-19 in less than two months, 95% of which were attributable to the Delta variant of the virus. The PHHPC found that the presence of unvaccinated personnel in health care facilities posed "an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications." In line with those findings, § 2.61 contained only a limited medical exemption—and no religious exemption—to the vaccination requirement.

Plaintiffs are five anonymous health care workers, employed by New York Presbyterian Healthcare System, Inc., Trinity Health, Inc., and Westchester Medical Center Advanced Physician Services, P.C. (collectively, the "Private Defendants"), who objected to the vaccination requirement on religious grounds. All of the Private Defendants amended their policies in order to comply with § 2.61 and, as a result, denied Plaintiffs' religious exemption requests or revoked exemptions that had been granted under their pre-existing vaccination policies.

On Sept. 10, 2021, Plaintiffs filed suit against Gov. Kathy Hochul and former Commissioner of Health Howard Zucker (collectively, the "State Defendants"), as well as the Private Defendants, in the U.S. District Court for the Eastern District of New York. Plaintiffs alleged that the Mandate violates the Free Exercise Clause of the First Amendment and the Equal Protection Clause of the Fourteenth Amendment and is preempted by Title VII of the Civil Rights Act of 1964. Plaintiffs also brought Title VII claims against the Private Defendants, alleging that they failed to accommodate Plaintiffs' religious beliefs by denying their requests for religious exemptions or revoking exemptions that had previously been granted. Finally, Plaintiffs brought conspiracy claims against all Defendants under 42 U.S.C. § 1985(3). Defendants moved to dismiss.

The court first addressed Plaintiffs' First Amendment claim. It began its analysis with a discussion of the Supreme Court's landmark ruling in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) and multiple subsequent decisions that stand for "the principle that governments have the power to enact mandatory vaccination policies to protect the public health in the face of a public health emergency." The court went on to explain that the Free Exercise Clause "does not relieve an individual of the obligation to comply with a 'valid and neutral law of general applicability'" simply because it requires conduct that violates his or her faith.

Reviewing the Mandate, the court found it to be "neutral on its face" because § 2.61 does not reference religion and applies to "all persons employed or affiliated with a covered entity" who have the potential to expose patients, residents, or co-workers to COVID-19, except for those individuals for whom the vaccine is medically contraindicated. The court also held that Plaintiffs had cited "no evidence to suggest that the state's purpose in enacting Section 2.61 was to suppress or discriminate against the exercise of religion," as opposed to "protecting the public" from "exposure to a highly contagious and potentially fatal infection." The court noted that the PHHPC's decision not to include a religious exemption in the Mandate was consistent with multiple other vaccine mandates imposed on New York State health care workers, such as the requirement to be immunized against measles and rubella, which similarly lack a religious exemption.

Likewise, the court found the Mandate to be generally applicable. The court asserted that a law is not generally applicable if it "prohibits religious conduct while permitting secular conduct that undermines the government's asserted interests in a similar way" or provides a "mechanism for individual exemptions." Plaintiffs alleged that by permitting medical exemptions but not religious exemptions, the State Defendants treated "comparable" secular conduct more favorably than religious conduct and undermined their alleged interest in public safety by allowing medically exempted, unvaccinated workers to remain in their patient- and staff-facing roles. The court rejected this argument, finding it "self-evident that requiring an employee to be vaccinated even if the employee has a documented medical condition that makes vaccination unsafe would not promote the interest in protecting healthcare workers" or "avoiding staffing shortages." The court further rejected Plaintiffs' claim that the Mandate "creates a system of individualized exemptions," as § 2.61 provides "objective standards" for workers seeking a medical exemption, including a "certification from a physician or certified nurse practitioner attesting that they have a pre-existing health condition that renders the vaccination detrimental to their health, in accordance with generally accepted medical standards."

Given its determination that the Mandate is a neutral law of general applicability, the court applied rational basis review to Plaintiffs' First Amendment claim. The court found that "Section 2.61 easily meets this standard," and dismissed Plaintiffs' claim, in light of the extraordinary public health crisis caused by the COVID-19 pandemic.

For the same reasons, the court dismissed Plaintiffs' Equal Protection Clause claim. The court held that workers with medical contraindications to the COVID-19 vaccine are "not similarly situated" to religious objectors to the Mandate. The court also explained that "a law subject to an equal protection challenge" is analyzed under rational basis review where it "does not violate [the plaintiffs'] free exercise of religion."

The court then dismissed Plaintiffs' claim that the Private Defendants violated Title VII by purportedly failing to offer them reasonable religious accommodations. As a threshold matter, the court held that Plaintiffs' Title VII claim was subject to dismissal because they conceded that they had not exhausted their administrative remedies before the U.S. Equal Employment Opportunity Commission. The court went further, however, to rule that Plaintiff's Title VII claim "fail[ed] on the merits." The court observed that the "sole 'accommodation'" sought by Plaintiffs was "a religious exemption from the vaccine requirement." This accommodation "would impose an undue hardship on the Private Defendants"—and thus need not be provided—"because it would require them to violate state law." The court was also persuaded that exempting Plaintiffs from the vaccination requirement would impose undue hardship on the Private Defendants insofar as it would "expose vulnerable patients and nursing home residents, as well as other healthcare workers, to the COVID-19 virus."

The court then turned to Plaintiffs' claim that § 2.61 violates the Supremacy Clause of the U.S. Constitution. Plaintiffs argued that the Mandate "abolished the entire accommodation process under Title VII for religious objectors" to the vaccination requirement. The court first explained the Supremacy Clause is not the source of any substantive rights and does not create a federal cause of action. To the extent that Plaintiffs intended to make a federal preemption challenge to the Mandate, the court held that their claim still failed as a matter of law. The court asserted that Plaintiffs improperly "conflate[d] exemption with accommodation." While § 2.61 prohibits blanket religious exemptions to the vaccination requirement—which Plaintiffs sought—it "does not foreclose all opportunity for Plaintiffs to secure a reasonable accommodation under Title VII."

Finally, the court denied Plaintiffs' conspiracy claim under 42 U.S.C. § 1985(3). The court held that Plaintiffs could not maintain a cause of action for conspiracy because they had "not alleged a violation of the law."

[*Editors' Note: Garfunkel Wild, P.C. represented Defendant Westchester Medical Center Advanced Physician Services, P.C. in the* Does 1-2 *action*]

Appellate Division Reinstates Attorney General's Petition Against Wholesale Distributor for Price Gouging on the Sale of Lysol During the COVID-19 Pandemic

People by James v. Quality King Distributors, Inc., 209 A.D.3d 62 (1st Dep't 2022). Respondent Quality King Distributors, Inc. ("Quality King") is a wholesale distributor of various consumer products, including Lysol disinfectant, to national and local retailers. In February and March 2020, the New York State Attorney General (the "Attorney General") received consumer complaints regarding the price of Lysol at retailers who had purchased the product from Quality King. Pursuant to its authority to investigate and remediate price gouging under General Business Law (GBL) § 396-r and Executive Law § 63(12), the Attorney General sent a cease-and-desist letter to Quality King demanding that it stop charging excessive prices for disinfectants and later requested purchase and sale data.

In May 2020, the Attorney General commenced a special proceeding in the Supreme Court, New York County, alleging that Quality King engaged in price gouging for Lysol spray canisters. The Attorney General contended that there was an "abnormal disruption of the market for Lysol products" on Jan. 31, 2020, when the U.S. Department of Health and Human Services declared a public health emergency resulting from COVID-19, and that Quality King "unjustifiably sold the Lysol product for unconscionably excessive prices" after that date. These allegations were founded on Quality King's purchase and sale data, which demonstrated that prices were repeatedly raised despite relatively stagnant costs, resulting in an approximately 75% increase in gross profit margins between November 2019 and March 2020. The Attorney General sought injunctive relief, an accounting, restitution, disgorgement of profits, and a civil penalty.

Quality King interposed an answer to the petition and moved to dismiss. The Supreme Court denied and dismissed the petition, finding that despite "isolated instances of price increases," Quality King did not "uniformly raise [its] prices" in a way that would suggest the use of any unfair leverage, abuse of bargaining power, or unfair means. Furthermore, the court found that the "abnormal disruption in the market" occurred on March 7, 2020, not Jan. 31, 2020; that there was not a "gross disparity" between Quality King's pricing of the Lysol product before and after that date; and that Quality King demonstrated that it faced its own increase in costs for the Lysol product during that time period. Both parties appealed.

The Appellate Division, First Department began its analysis with an overview of GBL § 396-r. To establish a claim for a violation of that statute, the Attorney General must show: (1) an "abnormal disruption of the market for a particular good or service"; (2) that "the good or service was vital and necessary for the health, safety and welfare of consumers"; and (3) that "the alleged price gouger sold (or offered to sell) the vital and necessary good or service for an unconscionably excessive price, which is established by showing an unconscionably extreme amount of excess in price, an exercise of unfair leverage or unconscionable means, or both." Moreover, to establish a *prima facie* price gouging claim, the Attorney General must demonstrate either that there was a "gross disparity" between the price of the good immediately before and after the abnormal disruption or that the amount charged for the goods "grossly exceeded the price at which the same or similar goods . . . were readily obtainable by other consumers in the trade area." A party accused of price gouging may assert, as an affirmative defense, that the increased prices were justified by additional costs not within its control.

Turning to the merits, the Appellate Division determined that the "abnormal disruption of the market for the Lysol product" occurred on Feb. 26, 2020, when the U.S. Centers for Disease Control and Prevention warned that they expected to see community spread of COVID-19 in the United States. The court observed that GBL § 396-r(2) provides a "disjunctive" list of events that may cause an abnormal market disruption, including, among other things, a "national or local emergency," and that a "declaration of a state of emergency by the governor" is not required. The court found that as of Jan. 31, 2020—the date proposed by the Attorney General—the risk of COVID-19 had "not yet graduated to a national emergency" within the meaning of the statute. On the other hand, the appellate court rejected the date selected by the Supreme Court—March 7, 2020, when then-Governor Cuomo declared a state disaster emergency—because the national emergency began on an earlier date. The court reasoned that employing the later date "would be improper in light of the remedial nature of the price-gouging statute, and because it would potentially permit a period of price-gouging to go unchecked."

Next, the court held that the Lysol product was "vital" and necessary" for purposes of GBL § 396-r. The court stated that "consumers in the first several months of 2020 had good reason to believe that the virus could be killed if a surface were treated with a disinfectant," and thus the Lysol product was, "in the eyes of consumers, of the utmost importance and absolutely needed to address the terrible danger posed by COVID-19."

Then, the court reviewed the purchase and sale data in the record and found "several instances" where there was a "gross disparity" between the price of Lysol immediately before and after the abnormal market disruption on Feb. 26, 2020. As different prices were charged to different retailers, the court held that each transaction for the Lysol product after that date must be compared to the price charged to the same customer in the usual course of business before the disruption occurred.

Having held that the Attorney General established all three elements of a claim for violation of GBL § 396-r, the Appellate Division reversed the dismissal of the petition and remanded to the Supreme Court for further proceedings. The Appellate Division also noted that the Supreme Court may order an accounting or an evidentiary hearing to assess the extent of any monetary remedies that may be warranted.

Finally, the Appellate Division considered, and rejected, Quality King's contention that certain terms in GBL § 396-r are unconstitutionally vague. The court stated that a statute is "impermissibly vague," and thus violates the Due Process Clause, if it "fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits" or if it "authorizes or even encourages arbitrary and discriminatory enforcement." Economic regulations, however, are entitled to a "relaxed vagueness test" because businesses "can be expected to consult relevant legislation in advance of action." Thus, an economic regulation is invalid only where it is "so vague and indefinite as really to be no rule or standard at all." Using that relaxed test, the court concluded that the challenged provisions of GBL § 396-r are sufficiently clear. Although the statute does not provide a "quantitative metric" as to whether a price is "unconscionably excessive or unconscionably extreme," the court asserted that the "absence of such a metric . . . does not affect the statute's constitutionality."

Appellate Division Rejects DOH Methodology for Review of Medical Marijuana License Application

Hudson Health Extracts, LLC v. Zucker, 206 A.D.3d 1515 (3d Dep't 2022). In 2014, New York passed the Compassionate Care Act (the "Act") to regulate the state's medical marijuana industry. The Act established extensive criteria for the Commissioner of Health (the "Commissioner") to consider when evaluating applications for licensure to manufacture and dispense approved medical marijuana products. Among other factors, the Commissioner must consider the applicant's ability to "maintain effective control against diversion of marihuana [and] properly carry on the manufacturing or distributing activity for which [licensure] is sought," along with whether the applicant possesses "sufficient land, buildings, and equipment to properly carry on the activity described in the application." The Act called for initial approval and registration of five organizations, after which the Commissioner maintained discretion to grant additional licenses.

In April 2015, the Department of Health (DOH) solicited applications with the goal of approving up to five new licenses. Petitioner was one of 43 applicants. The DOH conducted an intricate review process, during which it scored applicants in 11 separate categories. For some categories the DOH used a simple pass/fail system, and for others it employed a 0-3 point scale. The DOH then weighted each category to develop a final score. Ultimately, Petitioner ranked 13th among the 43 applicants, resulting in the denial of its application.

An Administrative Law Judge (ALJ) sustained the denial on appeal, ruling that the DOH used a rational scoring methodology and that the underlying evidence supported the DOH's denial of Petitioner's application. Petitioner commenced an Article 78 proceeding after the Commissioner adopted the ALJ's recommendation in full. The Supreme Court transferred the Article 78 proceeding to the Appellate Division, Third Department, pursuant to CPLR 7804(g).

Petitioner did not challenge the underlying evidence, but rather the methodology used by the DOH to score the "financial standing" section of its application, which comprised 9.6% of its overall score. Specifically, Petitioner argued that it was in a superior financial position than other applicants but received the same score because the DOH failed to conduct a substantive examination of its financial disclosures.

On review, the Third Department applied the well-established standard that "an agency's action is arbitrary and capricious when it is taken without sound basis in reason or regard to the facts." In doing so, the court emphasized that the governing DOH regulations require consideration of whether an applicant "can produce sufficient quantities of approved medical marihuana products as necessary to meet the needs of certified patients" and is "ready, willing, and able to properly carry on the activities set forth" in the regulations. The court found that both considerations "necessarily require an accounting of the applicant's financial wherewithal."

The court then detailed the three-step methodology utilized by the DOH to assign "financial standing" scores. The first two steps required applicants to submit financial disclosure forms, namely: (1) "a financial statement setting forth all elements and details of any business transactions connected with the application"; and (2) "the most recent certified financial statement of the applicant . . . including a balance sheet as of the end of the applicant's last fiscal year and income statements for the past two fiscal years." The DOH scored these submissions on a pass/fail basis, with applicants receiving two points (i.e., a passing score) for submission of both required disclosure forms. According to testimony from the DOH's program director, a third step in the scoring process called for a substantive, independent review of the applicant's financial disclosures. Evidently, the DOH did not implement this third step with respect to Petitioner's application.

Despite this omission, the ALJ upheld the DOH's decision, reasoning that "the highest score given any applicant . . . was a raw score of 2 points when the application contained both financial statements," and that neither the statute nor governing regulations "required [the DOH] to rank an applicant higher if the applicant could demonstrate that it possessed superior financial resources." Thus, despite Petitioner's balance sheet indicating "that it was in a superior financial position to that of many other applicants—amassing approximately $18.6 million in assets toward the endeavor," Petitioner did not establish that it was entitled to a higher score than other applicants. In other words, mere submission of the required financial disclosure forms entitled an applicant to two points, with no upward or downward adjustments based on the substantive data contained therein.

The Third Department rejected the ALJ's analysis because it "completely fail[ed] to account for part 3"—that is, the substantive financial review described by the DOH's program director. The court likewise rejected the Commissioner's argument that the DOH regulations do not expressly require a substantive financial review, finding not only that the DOH "create[d] a scoring methodology that directly contemplated such a review," but that "the regulations also implicitly do so by requiring DOH to consider whether the applicant is able to" produce sufficient quantities of approved products and is "ready, willing, and able" to perform. Therefore, the court held, "[t]o simply reason that an applicant gets [two points] for attaching the required financial statements, regardless of the information contained therein, ignores the need to substantively evaluate the applicant's actual financial standing—*i.e.*, the capacity and wherewithal to implement the program in accordance with DOH's own regulations."

Accordingly, the court held that the DOH's "determination regarding the financial standing portion of Petitioner's application [was] arbitrary and capricious and must be annulled." With respect to the appropriate remedy, the court denied Petitioner's request to award three points for financial standing, which, based on the DOH's weighting system, would have placed Petitioner in the top five applicants and automatically entitled Petitioner to a license. Instead, "given the technical and specialized nature of the program at issue, and mindful of the agency's expertise in this area," the court remitted the matter to the DOH to perform a "substantive financial review" and "issue a new determination as to Petitioner's financial standing score, as well as any related change to its overall score, and whether to grant Petitioner a license."

UnitedHealth Defeats Class Action Alleging It Was Required to Pay Facility Fees for Medical Office-Based Surgeries

Med. Soc'y of the State of N.Y. v. UnitedHealth Group, Inc., No. 16 Civ. 5265, 2022 WL 4234547 (S.D.N.Y. Sept. 14, 2022). Two organizations—the Medical Society of the State of New York and the Society of New York Office Based Surgery Facilities—and one New York City medical practice brought a class action lawsuit in the U.S. District Court for the Southern District of New York against UnitedHealth Group Inc. and related entities (collectively, "United"). Plaintiffs alleged that United was required, under the terms of its health benefits plans and the Employee Retirement Income Security Act of 1974 (ERISA), to pay "facility fees" to out-of-network physicians who perform surgeries at their own medical offices, but failed to do so. Following a five-day bench trial held in February 2022, and the submission of post-trial briefs, the court found in favor of United on all counts.

United administers multiple ERISA-governed health benefit plans, the majority of which are self-funded by the plan sponsor. Although the terms of those plans vary somewhat, they all distinguish between "facilities" and "physician offices." In most of United's plans, only hospitals and "alternate facilities" are entitled to collect facility fees, and "physician's office services" is listed as a separate coverage item. None of the plans expressly states that a physician's office is a "facility" entitled to separate facility fees.

Furthermore, all of United's plans employ one of two reimbursement methodologies for out-of-network providers—(1) a percentage of the Medicare rate or (2) a percentage of the "reasonable and customary" charges for the services at issue—and neither allows for payment of a separate facility fee to a physician's office for an office-based procedure. Under Medicare's rules, physicians are paid a "global professional fee," which includes, for office-based surgeries, compensation for the physician's "practice expense" of, among other things, supplies and overhead costs. When the surgery is performed at a hospital or ambulatory surgical center, the global professional fee is reduced to reflect that these costs are borne by the facility and not by the practice. Likewise, when United's plan calls for reimbursement at a percentage of "reasonable and customary charges," United estimates the practice expense based on a "professional charge database" and includes that expense as part of a global professional fee for office-based surgeries.

In or about 2005, United became aware that some physician's offices were using the "facility code" when billing their claims in order to collect a facility fee. United's in-house counsel testified that this prompted a review of its plans and applicable law to determine whether such fees should be paid.

United confirmed that none of its plans required it to pay a facility fee to a physician's office and that no client plan sponsor had ever requested that United do so. As a result, United changed its standard claim adjudication process to flag these charges and deny the facility fee absent proof of facility licensure. And, in 2007, when New York enacted new legislation addressing office-based surgeries, United considered that law and concluded that it did not require the payment of facility fees to physician's offices.

Plaintiffs brought a class-wide claim against United for declaratory and injunctive relief, alleging United "systematically violated ERISA by failing to adequately review the plans to determine whether facility fees should be paid to physician offices for office-based surgeries." The medical practice also separately asserted a claim under ERISA for the payment of more than $1.5 million in facility fees.

The court began its analysis with the legal standard on ERISA claims. When the administrator is granted discretionary authority to interpret the terms of the plan, the denial of benefits may be overturned only if it is arbitrary and capricious. Moreover, ERISA's Claim Procedures Regulation requires plan administrators to "'establish and maintain reasonable procedures' for processing benefit claims, including 'administrative processes and safeguards designed to ensure and to verify that benefit claim determinations are made in accordance with governing plan documents.'" As such, the court needed to "determine whether United's procedures were reasonable, according deference to determinations as to which United may exercise its discretion."

Addressing the class-wide claim, the court held that Plaintiffs failed to meet their burden to prove that United's procedures were unreasonable. The court found that United sufficiently reviewed the plan terms, implemented reasonable systems designed to ensure that coverage determinations were made in accordance with those terms, and sufficiently explained to Plaintiffs why they were denied facility fee claims submitted for office-based procedures. The court also held that United's conclusion that Plaintiffs were not entitled to facility fees was reasonable, as none of the plans at issue expressly required United to pay facility fees to physician's offices and many clearly precluded it. The court found that United's determination was consistent with Medicare conventions, the practices of other insurers, and New York law.

Having ruled against Plaintiffs on the class-wide claim, the court turned to the New York City medical practice's individual claim for ERISA benefits. Because the practice was not a licensed facility under Article 28 of the New York Public Health Law, the court held that it was not entitled to facility fees from United for the surgeries performed at its office.

Whistleblower Claim Alleging that McKesson's Free Business Management Tools Constituted Illegal Kickbacks to Oncology Practices Is Dismissed With Leave to Replead

United States, ex. rel. Hart v. McKesson Corp., No. 15 Civ. 903, 2022 WL 1423476 (S.D.N.Y. May 5, 2022). A former employee of McKesson Corporation ("McKesson") filed a *qui tam* lawsuit against the company and related subsidiaries in the U.S. District Court for the Southern District of New York, alleging that McKesson offered business-management tools exclusively to oncology practices committed to purchasing a significant portion of their drugs from McKesson, in violation of the Anti-Kickback Statute (AKS).

McKesson sells pharmaceuticals, medical supplies, and other services to health care providers. As alleged in the complaint, McKesson Specialty Health, a business unit of McKesson, generated its largest line of its revenue from the oncology business. As a part of this business, McKesson offers commitment programs in which oncology practices must commit to buy a certain volume of their oncology drugs from McKesson. In turn, McKesson provides the oncology practices free use of two of McKesson's business-management tools—the Margin Analyzer (which, among other things, allowed the oncology practice to compare the reimbursement rates of interchangeable drugs) and the Regimen Profiler, (which allowed the oncology practice to calculate the profit margins for the entire course of treatment, including non-drug costs).

Plaintiff-Relator sued on behalf of the federal government and multiple states, asserting that McKesson's policy of offering the tools exclusively to commitment program members violated the AKS, a criminal statute that makes it illegal to knowingly and willfully offer or pay remuneration for items or services reimbursable by a federal health care program. Plaintiff-Relator asserted that any claims for reimbursement submitted to the government in connection with this policy were "false" under the False Claims Act (FCA), a federal law that imposes civil liability for knowingly submitting a false or fraudulent claim to the government.

McKesson moved to dismiss, contending that Plaintiff-Relator's complaint was deficient in three respects: (1) it failed to plausibly allege that the business-management tools constituted remuneration; (2) it failed to plausibly allege that McKesson acted with the required scienter; and (3) it failed to plead the fraudulent scheme with particularity. The court granted McKesson's motion to dismiss, holding that Plaintiff-Relator failed to allege the element of scienter, but afforded Plaintiff-Relator leave to amend the complaint.

The court explained that because Plaintiff-Relator's FCA claim was based on a violation of the AKS, Plaintiff-Relator was required to satisfy the pleading requirements for both statutes. On the issue of scienter, the parties disputed what mental state is required to allege a "willful" violation. Plaintiff-Relator argued that he must plead only "that the defendant willfully committed an act that violated the AKS," while McKesson argued that willfulness requires McKesson to have acted "with an intent to do something unlawful." The court held that the term "willful" required Plaintiff-Relator to plead facts that give rise to a plausible inference that McKesson knew its conduct was unlawful, although he need not allege that McKesson acted with specific knowledge of the AKS. Applying this standard, the court agreed with McKesson that Plaintiff-Relator failed to plead willfulness. While the complaint alleged that McKesson generally knew giving remuneration to induce purchases was illegal, the factual allegations—including that McKesson operated the alleged policy openly and took no action to conceal the purported fraudulent scheme—belied Plaintiff-Relator's contention that McKesson knew its policy violated the law. The court therefore held that dismissal was required.

The court also evaluated—and rejected—McKesson's other motion to dismiss arguments. The court held that Plaintiff-Relator sufficiently alleged that the free tools constituted remuneration under the AKS because he pleaded facts establishing that they had "substantial value" to customers "apart from the products offered by McKesson." Likewise, the court held that the tools' value was not "virtually meaningless" without McKesson's products and specifically noted that the complaint alleged that at least one customer sought access to the tools after ending its commitment program. Furthermore, the court declined McKesson's request to take judicial notice of other entities' free tools, which McKesson claimed were comparable, since McKesson was not simply asking the court to acknowledge the tools' existence, but was asking for a factual determination that the tools were similar. The court held that this argument was inappropriate on a motion to dismiss.

Lastly, with regard to the submission of claims to the government, McKesson argued that Plaintiff-Relator needed to allege specific false claims that were submitted. The court disagreed, finding that a plaintiff need only plead: (1) facts sufficient to support an inference that false claims were submitted; and (2) that the information capable of identifying those claims is peculiarly within the defendant's knowledge. The court held that Plaintiff-Relators' allegations, which included details from the records made available during his employment at McKesson, met this pleading standard because they suggested McKesson knew that its customers were routinely submitting claims to Medicare and other federal health care programs.

Second Circuit Upholds FOIA Redactions to Documents Submitted in Connection with New Drug Application, Finding Sufficient Evidence of Foreseeable Harm to Submitter's Commercial or Financial Interests

Seife v. U.S. Food & Drug Admin., 43 F.4th 231, 234 (2d Cir. 2022). In 2007, Sarepta Therapeutics, Inc. ("Sarepta") submitted an Investigational New Drug Application to the FDA for Exondys 51, a drug developed by Sarpeta to treat Duchenne muscular dystrophy (DMD), a fatal neuromuscular disease that affects young and adolescent males. On September 19, 2016, following a nine-year approval process in which Sarepta submitted tens of thousands of documents, the U.S. Food and Drug Administration (FDA) granted accelerated approval for the drug.

In December 2016, Plaintiff-Appellant Charles Seife, a science writer and journalism professor, submitted a request to the FDA and the U.S. Department of Health and Human Services (HHS) pursuant to the Freedom of Information Act (FOIA), seeking documents submitted by Sarepta as part of the approval process. At the same time, Seife requested expedited processing on his FOIA request. On December 21, 2016, the FDA denied Seife's request for expedited processing. Plaintiff-Appellant appealed that denial administratively and, on April 25, 2017, the FDA denied his appeal.

On May 25, 2017, Seife filed suit against the FDA and HHS in the U.S. District Court for the Southern District of New York, challenging the denial of expedited processing and what was "tantamount to a constructive denial of his FOIA request." After Seife moved for partial summary judgment on his expedited processing claim, the FDA granted his request, and the parties agreed to a schedule for producing documents responsive to a "narrowed FOIA request." Thereafter, the FDA produced approximately 45,000 pages to Seife, but redacted some pages pursuant to FOIA exemptions. On September 15, 2017, Sarepta moved to intervene as a defendant, which the district court granted.

Seife challenged certain redactions that the FDA made to those documents under Exemption 4 of the FOIA, which shields from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." The parties submitted cross-motions for summary judgment regarding those redactions. On October 6, 2020, the district court granted Defendants' motion for summary judgment and denied Seife's motion for summary judgment. The district court concluded that Defendants demonstrated that the redacted information fell within Exemption 4 and met the additional requirement, set by the FOIA Improvement Act of 2016 (FIA), that an agency shall withhold information under the FOIA only if it "foresees that

disclosure would harm an interest protected by an exemption" or if disclosure is "prohibited by law." Seife appealed.

The U.S. Court of Appeals for the Second Circuit began its analysis by discussing the "two primary competing district court interpretations of the interests protected by Exemption 4": (1) "the submitter's economic or business interests"; and (2) "the information's confidentiality—that is, its private nature." Although Seife did not dispute that the redacted information fell within the scope of Exemption 4, he urged the court to adopt the first approach, contending that to "meet the additional burden imposed by the FIA," an "agency must show harm through 'diminution in the economic value of a submitter's intangible property' calculated in the same way as monetary damages." Defendants argued that such showing was unnecessary, in line with the second approach, asserting that the interest protected by Exemption 4 is "the confidentiality of the information itself."

The Second Circuit held, as a matter of first impression for the appellate courts, that "the interests protected by Exemption 4 of FOIA are the commercial or financial interests of the submitter in information that is of a type held in confidence and not disclosed to any member of the public by the person to whom it belongs." The court first parsed the language of Exemption 4 and asserted that its "plain text . . . indisputably protects confidential information" and "contemplates harm specifically to [the] commercial or financial interests" of the submitter. Thus, an agency can meet the foreseeable harm requirement of the FIA by showing foreseeable commercial or financial harm to the submitter upon release of the information in question.

Upon review of the record, the court concluded that Defendants presented sufficient evidence to establish foreseeable harm to Sarepta's commercial or financial interests. Specifically, Sarepta's declarations described how the information could be "used to develop studies" for similar drugs, be "used in competitors' head-to-head trials," or inform competitors "as to Sarepta's future clinical endpoint research." The court asserted that Seife failed to present any evidence to rebut defendants' showing of foreseeable harm, finding that "at most" he challenged "the degree of commercial or financial harm to Sarepta, rather than that such harm would result."

District Court Upholds New York City COVID-19 Vaccine Mandate for Department of Education Staff and City Employees Working in a School Setting

Kane v. de Blasio, No. 21 Civ. 7863, 2022 WL 3701183 (S.D.N.Y. Aug. 26, 2022). In August 2021, the New York City Commissioner of Health and Mental Hygiene (the "Commissioner") issued an order requiring Department of Education (DOE) staff, along with other city employees and contractors working in person in school settings, to provide proof of vaccination against COVID-19, or proof that they are on track to become fully vaccinated: (a) by Sept. 27, 2021, or (b) prior to beginning their employment (the "Mandate").

On Sept. 1, 2021, the United Federation of Teachers Local 2, AFT, AFL-CIO (UFT) filed a Declaration of Impasse and entered into arbitration with the City and the Board of Education of the City of New York (BOE), challenging the lack of religious exemptions to the Mandate. On Sept. 10, 2021, the City, the BOE, and the UFT reached an agreement that provided a procedure for seeking religious exemptions. Under this agreement, religious exemption requests were required to be documented in writing by a religious official. Exemption requests would be denied where the religious official had spoken publicly in favor of the vaccine; where documentation was readily available (e.g., from an internet source); or where the objection was personal, political, or philosophical in nature.

Plaintiffs filed suit in the U.S. District Court for the Southern District of New York, alleging that the Mandate violated their constitutional rights. Plaintiffs then sought preliminary injunctive relief, which the district court denied. On appeal, the Second Circuit found that Plaintiffs were unlikely to succeed on their argument that the Mandate is facially unconstitutional, but found merit to their "as applied" challenges and ordered a central citywide panel to reconsider their religious exemption requests adhering to the standards of Title VII of the Civil Rights Act of 1964, rather than the criteria set forth in the UFT arbitration agreement. The citywide panel subsequently reviewed the claims of the named Plaintiffs and generally determined that it would be an undue hardship, under Title VII, for the DOE to allow unvaccinated teachers to enter school buildings.

On Feb. 14, 2022, Defendants moved to dismiss Plaintiffs' complaint for failure to state a claim. In line with other courts that have upheld COVID-19 vaccine mandates, the court granted Defendants' motion and dismissed the action in its entirety.

Plaintiffs first alleged that the Mandate violated the First Amendment's Free Exercise clause. The court asserted that in order to prevail on a Free Exercise clause claim, a plaintiff must establish that the object of the challenged law is to infringe upon or restrict practices because of their religious motivation, or that its purpose is the suppression of religion or religious conduct. By contrast, the Free Exercise clause does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability. Where the government seeks to enforce a law that is neutral and of general applicability, it need only demonstrate a rational basis for its enforcement, even if enforcement of the law incidentally burdens religious practices.

The court noted that Plaintiff's arguments lacked merit because the Second Circuit had already found, on appeal of their motion for a preliminary injunction, that the Mandate is facially neutral and generally applicable. While Plaintiffs took the position that the Mandate had the "express purpose of inflicting special disability against minority religious viewpoints," the court determined there was no such evidence of "animus." Rather, the court found that the clear objective of the Mandate is to reduce the spread of COVID-19 in New York City schools and permit them to remain open. The court also rejected Plaintiffs' argument that the Mandate is not generally applicable based on exemptions carved out of the City's private employer vaccination mandate, as that was a separate mandate that applied to an entirely different group of people. Furthermore, the court rejected Plaintiffs' contention that the DOE's process for applying for individual exemptions requires strict scrutiny, because the citywide panel was instructed to adjudicate the exemption requests in accordance with the Title VII standard.

The court then held that rational basis review applied to Plaintiffs' claim. As it found that the DOE articulated a rational and compelling basis for the Mandate—namely, to allow schools to continue in person safely—Plaintiffs' Free Exercise Clause claim failed. The court also dismissed Plaintiffs' Establishment Clause claim, holding that it was "nothing more than a repackaging of plaintiffs' free exercise claims." The court likewise dismissed Plaintiffs' claim under the Equal Protection Clause, finding that they did not point to any "similarly situated persons who have been treated differently."

Next, the court turned to Plaintiffs' claim that the Mandate violated their substantive and procedural rights under the Due Process Clause. The court rejected Plaintiffs' substantive due process challenge because: (1) the Second Circuit and the Supreme Court have consistently recognized that the Constitution embodies no fundamental right that would render vaccine requirements imposed in the public interest, in the face of a public health emergency, unconstitutional; and (2) Plaintiffs cannot demonstrate that the state action was "so egregious, so outrageous, that it may fairly be said to shock the contemporary conscience . . . even were it accompanied by full procedural protection." Similarly, the court dismissed Plaintiffs' procedural due process challenge because there was no protected liberty interest at stake, adequate notice was provided, and any alleged deprivation could be fully remedied through the grievance procedures provided for in a collective bargaining agreement or through an Article 78 proceeding.

Finally, the court found that the Mandate was not unconstitutional as applied to Plaintiffs. The court noted that two Plaintiffs had their requests for religious accommodations granted and that five failed to avail themselves of the DOE process for seeking an exemption. The remaining Plaintiffs' claims were reviewed by the citywide panel. While Plaintiffs claimed that the citywide panel simply "rubber-stamped" their previous denials in "bad faith," the court determined that such assertions were insufficient to state a claim and contradicted by the record, which showed that the citywide panel reversed the denial of one Plaintiff's request. Moreover, all but one denial was based on a determination that the request presented an "undue hardship" because Plaintiffs, as school teachers, could not physically be in a classroom while unvaccinated without presenting a risk to the student population. The court found that the citywide panel's findings satisfied the requirements of Title VII because it appropriately determined that Plaintiffs' inability to teach their students safely in person imposed more than a *de minimis* cost on the DOE.

District Court Dismisses FMLA Claim by Employee Who Failed to Meet Hours Requirement as a Result of Wrongful Termination

Varecka v. CSX Transp., Inc., No. 21 Civ. 876, 2022 WL 1750700 (W.D.N.Y. May 31, 2022). Plaintiff is an employee of CSX Transportation, Inc. (CSX) who has a serious health condition and was granted intermittent leave under the Family and Medical Leave Act (FMLA). In 2018, CSX accused plaintiff of abusing his FMLA leave to take off time around holidays and terminated his employment. Plaintiff challenged his termination in arbitration pursuant to a collective bargaining agreement (CBA), resulting in two decisions where he was ordered to be reinstated and made whole. Following his reinstatement, Plaintiff again applied for FMLA leave, which CSX rejected because Plaintiff had not worked the requisite number of hours in the preceding year.

Plaintiff brought a putative class action against CSX in the U.S. District Court for the Western District of New York, alleging that CSX interfered with his and other employees' rights under the FMLA. Plaintiff claimed that the reason why he did not meet the criteria for FMLA leave is because of his wrongful termination. According to Plaintiff, CSX used the delay in the CBA arbitration process to its advantage in order to deny FMLA requests made by him and all similarly situated employees. CSX moved to dismiss, contending that Plaintiff failed to plead that he was an eligible employee under the FMLA.

The court noted that this case presented an issue of first impression in the Second Circuit: whether hours an employee would have worked but for a wrongful termination should count toward FMLA eligibility upon reinstatement. Under the FMLA, an eligible employee is one who has "been employed for at least 12 months . . . and for at least 1,250 hours of service with such employer during the previous 12-month period." Given the lack of binding authority, the court turned to FMLA's statutory and regulatory scheme to determine whether Plaintiff met the "hours of service" threshold to qualify as an "eligible employee." The court observed that the FMLA regulations provide only "one limited circumstance" where hours that an employee "'would have worked" are expressly credited: when an employee returns from military service covered by the Uniformed Services Employment and Reemployment Rights Act.

The court then looked to the Fair Labor Standards Act (FLSA) to determine Plaintiff's "compensable hours of work." The court noted that while the FLSA does not define "hours of service," its basic principle is that employees are entitled to compensation only for "physical or mental exertion" that is "controlled or required by the employer" for the benefit of its business. Conversely, the court noted, periods in which an employee is "completely relieved from duty and which enables them to use their time for their own purposes are not hours worked" under the FLSA. The court found that "these definitions appear to exclude hours Plaintiff would have worked between his termination and reinstatement from counting as 'hours of service' under the FMLA."

After discussing relevant case law from the First and Sixth Circuits, the court turned to two Second Circuit decisions addressing "two analogous issues." In the first of those cases, *Woodford v. Community Action of Greene County, Inc.*, the Second Circuit struck down a FMLA regulation providing that an employee lacking the minimum work hours to qualify for leave could still be deemed eligible if the employer incorrectly confirmed his or her eligibility or failed to provide timely notice of his or her ineligibility. The Second Circuit held that this regulation impermissibly expanded the scope of the FLSA and was thus contrary to the express intent of Congress, but it nonetheless held that the FMLA "leaves space" for rulemaking that may cure noncompliance with notice requirements by "creating a right of estoppel." In a subsequent case, *Kosakow v. New Rochelle Radiology Associates, P.C.*, the Second Circuit held that an employer may be estopped from challenging an employee's eligibility for leave because of the employer's misconduct in failing to post FMLA-required notices. The Second Circuit found that even if the plaintiff did not meet the 1,250-hour eligibility requirement, "nothing prevents a court from exercising its equitable estoppel powers to estop a party from raising a particular claim or defense."

In light of the *Woodford* and *Kasakow* decisions, the court held that Plaintiff could succeed only if he establishes "all of the elements" of an equitable estoppel claim. As Plaintiff did not plead those elements, the court granted CSX's motion to dismiss. Although Plaintiff did not ask to amend his complaint, the court afforded him the opportunity to make a motion for leave to amend consistent with its ruling.

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